

TFee 1625
Patent

Attorney Docket No. 1662/55002

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		Docket Number: 1662/55002	
Application Number 10/016,752	Filing Date October 30, 2001	Examiner Taylor V. Oh	Art Unit 1625
Invention Title NOVEL CRYSTAL AND SOLVATE FORMS OF ONDANSETRON HYDROCHLORIDE AND PROCESSES FOR THEIR PREPARATION	Inventors Ramy Lidor-Hadas et al.		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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22313-1450 on Feb. 27, 2006
Date: _____
Signature: Sharon T. Huang
Sharon T. Huang

Sir:

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. Copies of patents, publications or other information listed on the modified PTO Form 1449 are enclosed, unless indicated otherwise.

3. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due the Commissioner is authorized to charge deposit account number **11-0600** for such fees.

Respectfully submitted,

Date: 2/27/06

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Substitute for form 1449A/PTO		Complete if Known		
		<i>PCT</i>	Application Number	10/016,752
		<i>Filing Date</i>	October 30, 2001	
		<i>First Named Inventor</i>	Ramy Lidor-Hadas et al.	
		<i>Art Unit</i>	1625	
		<i>Examiner Name</i>	Taylor V. Oh	
		<i>Attorney Docket Number</i>	1662/55002	
(Use as many sheets as necessary)				
Sheet	1	of	2	

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		EP 0 276 559 B1	08-03-1998	Tyers		
		EP 0 415 522 B1	03-06-1990	Collin		
		WO 02/36558 A2 (U.S. equivalent 2002/0107275)	05-10-2002	Lidor-Hadas et al.		
		WO 02/055492 A2 (U.S. equivalent 2002/0115707)	07-18-2002	Lidor-Hadas et al.		
		WO 03/090730 A1	11-06-2003	Ndzie et al.		

Examiner Signature		Date Considered	
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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <small>(Use as many sheets as necessary)</small>		Application Number 10/016,752			
		Filing Date October 30, 2001			
		First Named Inventor Ramy Lidor-Hadas et al.			
		Art Unit 1625			
		Examiner Name Taylor V. Oh			
Sheet	2	of	2	Attorney Docket Number 1662/55002	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
		Pirttimaki, J., et al. "The Transformation of Anhydride and Hydrate Forms of Caffeine at 100% RH and 0% RH, <i>European Journal of Pharmaceutical Sciences</i> , 1994, Vol. 1, pp. 203-208		
		Iida, H., et al. "Intramolecular Cyclization of Enaminones Involving Arylpalladium Complexes. Synthesis of Carbazoles" <i>J. Org. Chem.</i> 1980, Vol. 45, pp. 2938-2942		
		European Pharmacopoeia 4.4, Ondansetron Hydrochloride Dihydrate" 2003, pp. 3489-91,		
		Harry G. Brittain (Ed.) (1999) "Polymorphism in Pharmaceutical Solids" Drugs and the Pharmaceutical Sciences Vol. 95, pp. 183-226, Marcel Dekker, Inc. New York, New York		
		Byrn, S.R., et al. (Ed.) (1999) "Solid-State Chemistry of Drugs" Second Edition, pp. 59-67, SSCI, Inc. West Lafayette, Indiana		
		Byrn, S.R., et al. (Ed.) (1982) "Solid-State Chemistry of Drugs" pp. 6-7, Academic Press, New York, New York		
		Threlfall, T.L., et al. "Analysis of Organic Polymorphs" <i>The Analyst</i> , 1995, Vol. 120, pp. 2435-2460		
		Carless, J.E., et al. "Cortisone acetate crystals forms" <i>J. Pharm. And Pharmacology</i> , 1966, Vol. 18, pp. 190S-197S		
		Chen, Chem Abstr. "Synthesis of Antiemetic Ondansetron" Chinese J. of Pharmaceuticals, 1993, 24(6), pp. 241-242 (Ch).		
		The United States Pharmacopeia (USP 27-NF22), 22 nd edition, First Supplement, April, 2004, pages 3030, 3075-3076		
		The United States Pharmacopeia (USP 27-NF22), 22 nd edition, Second Supplement, August, 2004, pages 3234, 3283-3285		
		The United States Pharmacopeia (USP 26-NF21), 21 st edition, The National Formulary, January, 2003, pages 1351-1352		
		The Merck Index p. 6977 "Ondansetron", 1996		
		Kim, M. Y., et al. "An Efficient Process of Ondansetron Synthesis" <i>Heterocycles</i> , 1997, Vol. 45, No. 10, p. 2041-2043		

Examiner Signature		Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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